

## **REMARKS**

Upon entry of the above amendments, claims 40-61 will be pending in the present application. Claims 45-48 are withdrawn from consideration.

### **I. Amendments**

Applicant has amended claims 40, 42-43, 49, 53-55, and 57. Claim 61 has been added. Claim 56 has been canceled. Support for these amendments can be found throughout the specification. Specifically, support for the added ratios of ingredients can be found in Example 15. No new matter has been added by these amendments.

### **II. Title**

Applicant has noticed that the title of the present application is incorrect on the Bibliographic Data Sheet (hereinafter the "Bib Sheet") entered on October 2, 2008 in the Image File Wrapper on the Patent Application Information Retrieval portal (hereinafter "PAIR") and also on the Application Data on PAIR. Applicant amended the title to the instant application in a Preliminary Amendment filed at the time the application was filed on March 30, 2004. The amended title is "Compositions for Treating Hormonally-Dependent Cancers." Applicant respectfully requests that this amendment be entered and acknowledged in an Official Filing Receipt.

### **III. Priority**

As noted in Applicant's Request for Continued Examination filed December 9, 2008, Applicant has amended the specification to include a priority statement that accurately reflects the chain of priority for the instant application. This priority information was included in Applicant's Preliminary Amendment filed at the time the present application was filed on March 30, 2004. Applicant has noticed that the Bib Sheet entered on PAIR on October 2, 2008 states that this application is "a DIV of 09/771,664." This appears to be a typographical error as the present application is a continuation-in-part application of PCT/US02/00476 which is a continuation-in-part application of U.S. Application No. 09/771,669. The '669 application, now

U.S. Patent No. 6,984,667, is a continuation-in-part application of U.S. Application No. 09/056,707, now U.S. Patent No. 6,689,748.

The Examiner acknowledged that the “Applicants have pointed out this application is a continuation-in-part of US application 09/771,669.” (Office Action, p. 9) Applicant respectfully requests that corrected priority claim also be acknowledged in an Official Filing Receipt.

#### **IV. Double Patenting Rejection**

The Examiner provisionally rejected claims 40, 43, and 49-51 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over co-pending U.S. Application No. 10/610,909. (Office Action, p. 3.) Applicant filed a terminal disclaimer for U.S. Application No. 10/610,909 with Applicant’s Request for Continued Examination filed December 9, 2008. The terminal disclaimer is available on the Image File Wrapper on PAIR, along with the other terminal disclaimer that was filed at the same time. Applicant respectfully requests that this double patenting rejection be withdrawn.

#### **V. Claim Rejections – 35 U.S.C. § 103(a)**

##### **A. Rejection of Claims 40, 43, and 49-51**

The Examiner has rejected claims 40, 43, and 49-51 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Florio (WO 97/21434), in view of Singh et al. (U.S. Patent No. 5,858,371), Nobile et al. (U.S. Patent No. 4,265,823) (in light of Dr. Duke’s phytochemical and ethnobotanical database), Widyarini et al., and Oka et al. (JP 06016531). Applicant respectfully traverses this rejection.

The Examiner has cited Florio for teaching an anti-inflammatory composition comprising chondroitin sulfate for symptomatic relief from arthritis. (*See* Office Action, page 4; Florio, abstract.) However, the Examiner has acknowledged that Florio “does not teach expressly the employment of quercetin, olive kernel extract, and isoflavonoids, such as genistein and phenoxodiol.” (Office Action, p. 4.) Thus, Florio also does not teach, suggest or provide a reasonable expectation that the ratios of the proteoglycan to the other ingredients in the

composition would be beneficial in treating the inflammatory components of a hormonally-dependent cancer.

The Examiner cited Singh et al. for disclosing “that quercetin is known to have anti-inflammatory activity.” (Office Action, p. 7.) The Examiner cited Nobile for disclosing “that estrole is a steroid which displayed anti-inflammatory properties.” (*See id.*) The Examiner also cited Widyarini and Oka for teaching that isoflavonoids, such as genistein, are anti-inflammatory agents. (*See* Office Action, p. 8.) However, none of these references teach, suggest, or provide a reasonable expectation that the ratios of the proteoglycan to the other ingredients in the composition would be beneficial in treating the inflammatory components of a hormonally-dependent cancer.

For the foregoing reasons, a person of ordinary skill in the art would not be able to combine Florio, Singh, Nobile, Widyarini, and Oka and come up with the ratios of ingredients as claimed to treat the inflammatory components of a hormonally-dependent cancer. As such, Applicant respectfully requests that the rejection under 35 U.S.C. § 103(a) be withdrawn.

#### **B. Claims 41, 42, 44, 52-60**

The Examiner has rejected claims 41-42, 44, and 52-60 as allegedly being unpatentable over Florio in view of Singh, Nobile, Widyarini, Oka, and further in view of Ip et al. Applicant respectfully traverses this rejection.

The Examiner stated that the Florio, Singh, Nobile, Widyarini, and Oka do not expressly teach the “employment of chemotherapeutic agent, such as tamoxifen.” (Office Action, p. 7.) As stated above, Florio, Singh, Nobile, Widyarini, and Oka – taken alone or in combination – do not teach, suggest, or provide a reasonable expectation that the ratios of the proteoglycan to the other ingredients in the composition would be beneficial in treating a hormonally-dependent cancer. Ip does not remedy this deficiency. Moreover, Ip does not teach, suggest, or provide a reasonable expectation that the ratio of proteoglycan to therapeutic agent as claimed would be beneficial in treating a hormonally-dependent cancer.

None of the cited references teach, suggest, or provide a reasonable expectation that the ratios of the proteoglycan to the other ingredients in the composition would be beneficial in treating a hormonally-dependent cancer. Therefore, Applicant respectfully requests that the rejection under 35 U.S.C. § 103(a) be withdrawn.

**CONCLUSION**

Applicant believes the rejections maintained in the Office Action have been overcome and that the application is in condition for allowance. The present invention is new, non-obvious, and useful. Applicant respectfully requests that a timely Notice of Allowance be issued.

Applicant believes no additional fees are due with this Response. However, if such a fee is due, or a credit is owed, the Director is hereby authorized to make them to our Deposit Account No. 08-0219, under Order No. 2003133.00125US10.

The Examiner is encouraged to call the undersigned at the telephone number given below to move this application towards allowance.

Respectfully submitted,

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